Supreme Court, U.S.
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No.

In the Supreme Court of the United States

AMGEN INC.,

Petitioner,

v.

HOECHST MARION ROUSSEL, INC. (now known as AVENTIS PHARMACEUTICALS INC.) and TRANSKARYOTIC THERAPIES, INC. (now known as SHIRE HUMAN GENETIC THERAPIES, INC.),

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In virtually every patent infringement case, federal district judges are called on to determine the scope of one or more claims in a patent. Such "claim construction" requires the judge to assess not only the state of the art and customary meaning of claim terms at the time of the invention, but also the contemporaneous meaning to a skilled practitioner of both the patent's technical description of the invention and the patent applicant's statements to the Patent and Trademark Office during the prosecution process. Many patent cases also include disputes over the "doctrine of equivalents," a significant doctrine that prevents a copyist from avoiding liability "by making only insubstantial changes to a patented invention." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 727 (2002); *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997).

This case raises two questions concerning the administration of these important doctrines and the allocation of judicial authority between trial and appellate courts:

1. Are all aspects of a district court's claim construction subject to *de novo* review, as the Federal Circuit has held despite vociferous criticism from numerous judges and commentators, or instead should the Federal Circuit have reviewed the factual determinations underlying the district court's claim construction deferentially?

2. By restricting the ways in which a presumption of "prosecution history estoppel" may be rebutted, and engaging in *de novo* review of a district court's determinations that the presumption *has* been rebutted, has the Federal Circuit effectively resurrected the categorical bar to a claim of infringement under the doctrine of equivalents that was expressly rejected in *Festo* and *Warner-Jenkinson*?

RULE 29.6 STATEMENT

Petitioner Amgen Inc. is a publicly traded corporation, and no publicly held corporation owns more than 10% of its stock.

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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The majority and dissenting opinions of the court of appeals (App. 1a-51a) are reported at 457 F.3d 1293. The opinions of the district court (App. 52a-335a) are reported at 339 F. Supp. 2d 202 and 287 F. Supp. 2d 126. Prior opinions of the court of appeals (App. 336a-415a) and the district court App. 416a-593a) are reported, respectively, at 314 F.3d 1313 and 126 F. Supp. 2d 69. The court of appeals' order denying rehearing and six dissenting and concurring opinions (App. 594a-609a) are reported at 469 F.3d 1039.

JURISDICTION

The judgment of the court of appeals was entered on August 3, 2006. The order denying rehearing (App. 595a) was entered on November 22, 2006. On January 29, 2007, Chief Justice Roberts extended the time to petition for a writ of certiorari to and including March 22, 2007. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

RULE INVOLVED

Federal Rule of Civil Procedure 52(a) states:

> In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon * * *. Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. * * *

STATEMENT

This is a case about the proper allocation of power between trial and appellate courts. Two issues that arise in most patent cases – claim construction and prosecution history estoppel – are decided by the court without a jury, but rest on factual findings. This case gives the Court an excellent opportunity to

resolve judicial disagreements about the standard by which the Federal Circuit should review those determinations, and to assess whether the Federal Circuit's reversal of careful and scientifically well-informed district court determinations on both issues comported with this Court's precedents.

In nearly every patent infringement case, a district court must construe the patent's claims – that is, determine their scope. Claim construction requires assessment of essentially factual matters, including: (1) the state of the art at the time of the invention; (2) the customary meaning of the claim terms at the relevant time; (3) the meaning of the patent specification (*i.e.*, the detailed technical description of the invention) to a skilled practitioner; and (4) the significance, again to a skilled practitioner, of the patent applicant's statements to the Patent and Trademark Office ("PTO") during the prosecution process.

In this case, the district judge drew on knowledge he had gained of scientific principles and terminology and carefully construed the term "therapeutically effective amount" in a patent claim in accordance with the understanding of skilled practitioners and the meaning they would give to the specification and prosecution record. A divided panel of the court of appeals, however, thought that the specification said something different. Ignoring all of the district court's detailed determinations, the majority announced a claim meaning broader than what the patent applicant stated was his invention and contrary to the understanding of skilled practitioners in the field. The result was a remand for a *third* trial on the validity of the claim.

What made this imperial act possible was the practice of reviewing claim constructions *de novo*, a practice that has been lambasted for years by bench, bar, and academy because – as this case glaringly demonstrates – it not only produces inaccurate results, but also misallocates judicial resources, spawns needless disputes, prolongs litigation, and destroys certainty. In *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996), this Court held that, although claim construction entails evidentiary inquiry, the exercise is better assigned to a trial judge than

a jury. The Federal Circuit has since read *Markman* to mean that claim construction is a purely legal exercise, and announced that it owes no deference to *any aspect* of a district court's claim construction. *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc).

But the Federal Circuit is wrong. Claim construction rests on factual determinations, appellate deference to which is *required* by Federal Rule of Civil Procedure 52(a) and this Court's precedents. The court of appeals' practice, therefore, is strong reason for this Court – which in *Markman* decided the proper role of judge and jury in claim construction – to take the logical next step and decide the proper roles of the trial and appellate courts. This case is a perfect opportunity.

The court of appeals also used *de novo* review to scrap a careful ruling regarding the doctrine of equivalents, which prevents a copyist from avoiding liability "by making only insubstantial changes to a patented invention." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 727 (2002); *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). *Festo* clarified that the right to claim infringement based on an "equivalent" invention is usually presumptively foreclosed by "prosecution history estoppel" if the patentee amended the patent during prosecution. But not all amendments surrender equivalents, and *Festo* set forth criteria for rebutting the presumption. The district court found those criteria satisfied because the rationale for the amendment in question had nothing to do with the equivalent at issue, and the patentee could not reasonably be expected to have literally claimed the equivalent. In reversing, the Federal Circuit effectively held that an amendment during prosecution surrenders anything beyond the claim's literal terms, thus resurrecting a categorical bar rejected in *Festo* and *Warner-Jenkinson*.

A. Factual Background

The patents at issue cover an anemia drug known as recombinant erythropoietin and manufactured by Amgen under the brand-name Epogen. Described by the district court as

"pathbreaking," App. 494a, the work of the inventor, Dr. Fu-Kuen Lin, provided the first product that could treat various forms of anemia, a condition in which the patient lacks "a steady, sufficient supply of red blood cells." In the body, natural erythropoietin ("EPO") stimulates the production of red blood cells; patients who fail to produce EPO become anemic. "The therapeutic goal for treating [such] patients * * * is to increase and maintain the production of red blood cells." App. 55a, 459a-460a.

Before Dr. Lin's breakthrough inventions, that goal had never been achieved. Small amounts of a form of EPO had been isolated from human urine by Dr. Eugene Goldwasser. When Goldwasser injected this "urinary EPO" into three anemic patients, there was only some suggestion of certain preliminary biological effects – including a reported increase in reticulocytes, the precursors to mature red blood cells – but no increase in any patient's "hematocrit," the ratio of red blood cell volume to total blood volume, which is the standard measure for anemia. In other words, the urinary EPO failed to treat anemia. Dr. Goldwasser eventually abandoned his study and testified that it was a failure. App. 55a, 260a-273a, 459a, 484a-487a. By contrast, the results of Dr. Lin's EPO were "dramatic beyond anyone's dreams." App. 493a (quoting respondents' witness). His EPO – much more potent than and structurally distinct from urinary EPO, and producible in commercial quantities – was "therapeutically effective because it was able to increase and maintain the patients' hematocrit level." App. 339a-340a, 460a, 486a n.27.

B. Earlier Proceedings

1. Amgen brought this action in 1997 seeking a declaration that respondents' EPO product infringed several of Dr. Lin's patents. One of them is U.S. Patent No. 5,955,422 (the '422 patent), Claim 1 of which reads (emphasis added):

> A pharmaceutical composition comprising a *therapeutically effective amount* of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant, or carrier, wherein

said erythropoietin is purified from mammalian cells grown in culture.

Chief Judge Young of the District of Massachusetts presided over the case. He selected a Massachusetts Institute of Technology professor as a technical advisor and "met privately with him for background tutorial assistance." App. 418a. He then conducted a three-day "*Markman* hearing" in which he received demonstrative exhibits and heard argument on ten key claim terms, App. 424a, and later held a 23-day bench trial that included testimony from 30 scientists. App. 419a, 454a-591a.

a. Judge Young found that respondents (collectively "TKT") infringed Claim 1 of the '422 patent. App. 453a. TKT contended that the claim was invalid under 35 U.S.C. § 102 because it was "anticipated" by – *i.e.*, not novel in light of – Goldwasser's urinary EPO. Judge Young rejected that argument because the Goldwasser subjects showed no increase in hematocrit, and "the accepted standard by which physicians measure a therapeutic response to EPO is an increase in hematocrit." Judge Young concluded: "Due to this lack of effect upon hematocrit levels, the patients did not appear to receive any health benefits from the reported biologic effects. * * * Consequently, the Goldwasser study could not anticipate any of Amgen's claims requiring a *therapeutically effective amount* of EPO." App. 484a-487a (emphasis added).

b. Judge Young also ruled that TKT infringed U.S. Patent No. 5,621,080 (the '080 patent) under the doctrine of equivalents. Judge Young found that TKT's product met every element of the relevant claims, except for a requirement that the protein have the "erythropoietin amino acid sequence of FIG. 6." Figure 6 of the specification depicts a DNA sequence coding for a polypeptide[1] having 166 amino acids. After the patent was filed, however, scientists learned that the last amino acid is usually cleaved off before the EPO molecule is released from the cell. Amgen's and TKT's EPO products thus have

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[1] A polypeptide is a molecule consisting of a chain of amino acids.

only 165 amino acids. Judge Young determined that the absence of the 166th amino acid was an insubstantial difference with no impact on the molecule's properties. App. 461a-464a, 524a-529a. At the same time, Judge Young rejected TKT's defense of prosecution history estoppel. Even though Amgen amended the patent during prosecution to add the Figure 6 reference to claims that had specified no sequence, the amendment was made solely to avoid potential redundancy with another of Amgen's patents – not the type of reason giving rise to estoppel under *Warner-Jenkinson*. App. 529a-533a.

In closing, Judge Young thanked the parties for teaching him about "the nuances of * * * this rather complicated realm of science." App. 591a.

2. a. In its first decision, the Federal Circuit agreed that TKT infringed the '422 patent, App. 391a, but vacated Judge Young's ruling that Goldwasser's urinary EPO did not anticipate Claim 1. The panel acknowledged, as TKT's experts conceded, that "[t]he therapeutic goal for treating anemic patients is to increase the 'hematocrit level,'" App. 339a – something Goldwasser did not do. But the panel said that the patent specification "appears to teach that results in addition to simply an increase in hematocrit can provide effective therapy." App. 400a.

The panel based that remark on a sentence that said: "to the extent that [the] products of the invention share the in vivo activity of natural EPO isolates" – *i.e.*, insofar as the claimed products produce biological effects similar to those associated with urinary EPO – they are "*suitable for use in [EPO] therapy procedures * * * to develop any or all of the effects here[to]fore attributed in vivo to EPO*, e.g. stimulation of reticulocyte response * * *, erythrocyte mass changes, * * * and, as indicated in Example 10, increasing hematocrit levels." '422 patent, col. 33 (emphasis added). The panel remanded for the district court to construe "therapeutically effective" in light of this sentence, and reevaluate whether Goldwasser's EPO anticipated Claim 1. App. 401a.

b. With respect to the '080 patent, the Federal Circuit held that, under this Court's intervening *Festo* decision, Amgen's amendment presumptively surrendered its claim to TKT's equivalent. The court remanded for a determination whether the *Festo* presumption is rebutted. App. 385a.

C. The District Court's Claim Construction Ruling

1. Judge Young concluded that the term "therapeutically effective amount" requires, *in addition to* certain in vivo[2] effects recited in the specification, "a result that in and of itself helps to heal or cure."[3] In arriving at this construction, Judge Young held another *Markman* hearing in which counsel used demonstrative exhibits and referred to expert testimony. The judge appointed a special master to assist with preparation of the next opinion – 53 pages of which are devoted to explaining his claim construction, see App. 70a-112a – and held a second, nine-day trial on other remanded issues. App. 67a-68a.

Judge Young followed the Federal Circuit's script for claim construction. He began with the term's plain and customary meaning, which he determined from technical and other dictionaries was an amount "that produces healing or curing as it relates to medical treatment of disease." App. 75a-82a. He then determined that the language of the patent claims, the specification, and the prosecution history each supported this meaning. App. 82a-109a. He repeatedly emphasized that his conclusions were informed by the expert testimony and his

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[2] "In vivo" (Latin for "in something living") simply means in a live organism, as opposed to "in vitro" (Latin for "in glass"), meaning in some kind of environment outside a living organism, such as a petri dish.

[3] Here is the court's construction in pertinent part (App. 112a):

> A therapeutically effective amount is a quantity that produces a result that in and of itself helps to heal or cure. A therapeutically effective amount is one that elicits in vivo biological activity of natural EPO such as those listed in the specification, column 33 * * *: stimulation of reticulocyte response, * * * erythrocyte mass changes * * * and * * * increasing hematocrit levels.

familiarity with the technology, even though expert testimony was not used "to define the term." *E.g.*, App. 85a, 86a n.28, 89a & n.29, 90a-91a & n.30, 109a n.46, 110a-111a n.47.

Judge Young did not think that the sentence to which the court of appeals had pointed equated each of the in vivo effects listed there with a "therapeutically effective" result. To conclude otherwise, he said, would be to endorse a "factually incorrect" proposition. Aside from the basic point that the sentence does not even use the term "therapeutically effective," urinary EPO was already known to elicit some of the listed effects but not an increase in hematocrit, which is how skilled practitioners measure EPO's therapeutic effectiveness. App. 90a-92a. Judge Young noted that "[e]xperts on both sides agree that the biological effects are surrogate markers or early indicators that a therapeutic effect will follow." App. 91a n.30. Therefore, he explained, "this part of the specification does not indicate that these biological responses are sufficient or that Amgen 'broadened' * * * 'therapeutically effective' to encompass the elicitation of biological effects alone regardless of whether they heal or cure." App. 91a-92a.

2. Finally, the district court found that Goldwasser did not anticipate Claim 1. From an exhaustive analysis of the technical testimony, App. 261a-273a, Judge Young concluded that any biological effects obtained by Goldwasser were not therapeutically effective but were "precursory responses before a therapeutic result is achieved." App. 273a.

D. The District Court's *Festo* Ruling

In a separate opinion (App. 278a-335a), Judge Young found that Amgen had rebutted the presumption of prosecution history estoppel that would otherwise have barred its claim of equivalent infringement of the '080 patent. In *Festo*, this Court described three situations in which the presumption is rebutted because "an amendment cannot reasonably be viewed as surrendering" the defendant's equivalent: (1) "the equivalent was unforeseeable"; (2) "the rationale underlying the amendment bears no more than a tangential relation to the equivalent in

question"; or (3) "some other reason * * * suggests that the patentee could not reasonably be expected to have described the insubstantial substitute." App. 294a.

After ruling against Amgen on the foreseeability criterion, Judge Young turned to the second criterion, noting that with this one, "more than the others," what counts is "the *purpose* of the amendment," not simply "whether the amendment itself narrows the * * * claim in a way that affects the equivalent in question." App. 317a-318a. Following a detailed examination of the prosecution history, he ruled for Amgen, finding that it had added the Figure 6 language not to exclude a 165-amino-acid EPO, but to distinguish the '080 patent from another patent known as the '933 patent on the basis that the '080 patent (unlike the '933) covered only *human* EPO. App. 319a-324a.

Judge Young also ruled for Amgen on the third *Festo* criterion. He agreed with TKT that Amgen *could have* drafted the claim differently, but explained that the final criterion calls for a "reasonableness inquiry" into what the patentee "*could be expected* to have done." App. 329a. Not only did the PTO know that the final form of EPO has 165 amino acids, but also, according to unrebutted expert testimony, Amgen's amendment would be understood by those skilled in the art to encompass EPO with a 165-amino-acid sequence. App. 329a-334a. Accordingly, "it would not be reasonable to expect Amgen to have drafted the claim differently." App. 331a.

E. The Federal Circuit's Panel Decision

1. a. Applying *de novo* review, and disregarding the district court's findings, the panel majority attempted, in four scant pages, to construe the claim term "therapeutically effective amount" from scratch. App. 12a-16a.

First, the panel returned to the portion of the specification quoted on page 6, *supra*, and found that it "supports the construction that the '422 patent encompasses a pharmaceutical composition which produces 'any or all' of the * * * listed effects," as opposed to an amount that produces any of those effects *and* treats or heals. App. 13a-14a. Second, the majority

sua sponte focused on another section of the specification, one dealing with protein "fragments duplicating only a part of" the full EPO sequence. These, the specification explains, "may possess one activity of EPO (e.g., receptor binding) and not others (e.g., erythropoietic activity). * * * [T]he absence of in vivo activity for any one or more of the 'EPO products' of the invention is not wholly preclusive of therapeutic utility (see, Weiland et al., supra)." '422 patent col. 36.[4] To the majority, this passage meant that "'therapeutic utility' is not dependent on the product having an effect in a living being." App. 15a. The majority then decreed that "the patentee used the words 'therapeutically effective' in order to broadly claim a pharmaceutical composition with a wide range of effects" that "do not *necessarily* include curing disease in humans." *Ibid.* Having redefined the claim, the panel again remanded for a finding whether the claim was anticipated by the Goldwasser study and therefore invalid under 35 U.S.C. § 102. App. 18a-19a.

b. Chief Judge Michel dissented, expressing "strong disagreement." He praised Judge Young's "meticulous attention" to the case and called his performance "a model for all trial courts." App. 43a-44a. Judge Michel agreed with the district court's analysis of the specification and prosecution history, and thought the district court "correctly recognized that merely eliciting a biological effect is not the same as being therapeutically effective." App. 44a. Judge Michel observed that the district court's construction "comports with the patentee's own repeated descriptions of the claimed invention. It is exactly the

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[4] The cited Weiland study, which the majority gave no indication of having read, showed that a relative of EPO, despite producing no in vivo effects by itself, induced red blood cell generation *when combined with another substance.* E. Weiland et al., *In Vivo Activity of Asialo-Erythropoietin in Combination with Asialo-Glycoproteins*, 44 BLUT 173 (1982). Hence, just as the patent said, the absence of in vivo effects from an EPO relative does not wholly preclude its potential use in therapy – which is not the same as saying that the relative on its own produces a therapeutically effective result.

way a skilled artisan would interpret the patent." App. 49a. Finally, he criticized the majority for prolonging litigation that "has already dragged on for almost ten years." App. 50a.

2. The court of appeals also reversed Judge Young's *Festo* ruling. App. 33a-40a. At oral argument, respondents conceded that, to the extent factual findings undergird a determination that the presumption of estoppel has been rebutted, they should be reviewed for clear error. In its opinion, however, the panel followed circuit precedent characterizing the estoppel inquiry as a question of law to be reviewed *de novo*. App. 33a. On the second *Festo* criterion, the panel disagreed that the rationale for amendment was tangential to the equivalent, because the addition of the Figure 6 reference "may have been central to overcoming a double patenting rejection," App. 37a. On the third criterion, the panel said that, even if (as Judge Young found) "the patentee, the examiner, or a person of skill in the art [would] have thought the claims encompassed EPO with 165 amino acids," that would "not excuse the patentee's failure to claim the equivalent. * * * [T]here was no linguistic barrier to claiming EPO comprised of 165 amino acids." App. 39a.

F. The Opinions Dissenting from and Concurring in the Denial of Rehearing En Banc

Amgen's petition for rehearing was denied but provoked six opinions in which four judges squarely criticized *de novo* review of claim constructions, three judges criticized limited aspects of the practice, and at least five judges disagreed with the panel majority's claim construction.

Chief Judge Michel's dissent questioned the rule of *Cybor Corp.* v. *FAS Techs., Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (en banc), that all aspects of a claim construction are reviewed *de novo*. He disputed *Cybor*'s "premise that claim construction is always a purely legal exercise, devoid of factual content":

> [T]he claim construction question often cannot be answered without assessing, at least implicitly, what the average artisan knew and how she thought about the particular technology when the patent claims were written.

> To make such determinations, the trial judge necessarily relies upon * * * evidence concerning the skill of the ordinary artisan at the relevant time. Indeed, trial judges are arguably better equipped than appellate judges to make these factual determinations, especially in close cases.

App. 596a-597. Judge Michel observed (App. 596a) that "four practical problems have emerged under" the *Cybor* regime:

> (1) a steadily high reversal rate; (2) a lack of predictability about appellate outcomes, which may confound trial judges and discourage settlements; (3) loss of the comparative advantage often enjoyed by the district judges who heard or read all of the evidence * * *; and (4) inundation of our court with the minutia of * * * disputed claim terms * * * in nearly every patent case.

Judge Rader's dissent also criticized *Cybor* and urged "deference to the factual components of the lower court's claim construction." App. 604a. "As is often the case," he explained, "the district court was better positioned * * * to reach the proper construction" because it "has more tools, more time, and more direct contact with factual evidence." *Ibid.* The trial court had heard testimony from "artisans informed of the meaning of 'therapeutically effective amount' at the time of invention," and Judge Rader found it significant that Judge Young, while disclaiming reliance on expert testimony, specifically noted that that testimony fully supported his claim construction. Given the Federal Circuit's rules discouraging resort to extrinsic evidence, Judge Rader remarked, "district court judges have learned to disclaim any reliance on expert testimony." App. 605a.

Judge Newman's dissent argued that the *de novo* standard "has not well withstood the test of experience." App. 601a. In her view (*ibid.*):

> [F]indings of science/technology-based facts in patent cases should receive appellate review on the same basis as other science-based findings * * *. The [Supreme] Court's and our own precedent require the trial judge to evaluate

> scientific evidence and expertise from the viewpoint of a person experienced in the field of science, a framework that aptly fits evaluation of the * * * scope of patents * * *.

Judge Newman also criticized the panel majority for broadening the claim when the PTO allowed the patent only because Dr. Lin distinguished his invention on the basis of its ability to heal or cure. App. 599a-600a. Judge Lourie, too, thought the panel majority had "incorrectly construed" the claim, but believed that the case did not merit en banc review. App. 603a.

Judge Gajarsa, joined by Judges Linn and Dyk, concurred. They did not endorse the panel's construction but were willing to reconsider only "limited aspects" of *Cybor*, namely the standard of review in "the atypical case" in which the claims, specification, and prosecution history "on their face did not resolve the question of claim interpretation, and the district court found it necessary to resolve conflicting expert evidence." Here, Judge Young "disavowed reliance on extrinsic expert evidence." The concurring judges believed that "[n]o deference is due a district court's legal interpretation of the claim language, written description, and prosecution history," because "an appellate court is equally competent to interpret" those materials. App. 606a-607a.

Judge Moore dissented. She praised Judge Young's efforts, criticized the lack of deference to them, and called for reconsideration of *Cybor*. Judge Moore, like Judge Rader, also found it significant that the district court "explain[ed] that the claim construction is supported by the expert testimony" but said that such testimony was being used only to "'understand the technology'" and not to "'define the term.'" App. 608a-609a.

REASONS FOR GRANTING THE PETITION

Plenary *de novo* review of claim construction does not work. It produces incorrect results and causes litigants and district courts to waste tremendous resources. The practice, which has been savaged by a sizable minority of the Federal Circuit, rests on the false premise that claim construction entails no factual inquiry. Construction of patent claims

depends on technological mastery and is therefore, like the inquiry into the reliability of scientific testimony under *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), something for which trial courts are uniquely suited and owed special deference. The Federal Circuit's simplistic syllogism – if an issue is for the court, it must be subject to complete *de novo* review on appeal – flies in the face of Rule 52(a) and is belied by well-established practice in patent and other areas of the law in which the factual determinations undergirding a court's legal pronouncement are reviewed for clear error.

This case exemplifies the perils of *de novo* review. The district court's determination was a product of acquired familiarity with a technical discipline. In the face of specification language that associated certain biological effects with "use in therapy procedures," the judge, drawing on all he had read, heard, and seen, concluded that one of skill in the art would not understand, and the PTO did not understand, that passage to define each of those effects as itself "therapeutically effective." But the panel, presuming to read the specification more competently than the district judge or the PTO, gave the passage in question a meaning contrary to the understanding in the field, and focused on – and flatly misunderstood – a different portion of the specification, one that neither the parties nor the district court had thought relevant in a decade of litigation. This Court's review is necessary to curb this type of overreaching and bring the Federal Circuit's approach to factual issues in line with that of other appellate courts.

The Federal Circuit's treatment of Judge Young's prosecution history estoppel ruling also raises important and recurring issues. Again without the benefit of the district court's special familiarity, the court of appeals failed to focus, as this Court has instructed, on the rationales for amendment and the reasonableness of the drafting. Instead the panel used *de novo* review to convert the former inquiry into an insurmountable tautology and the latter into a redundancy with a foreseeability test so narrow that it has never been satisfied. The decision strips both *Festo* and *Warner-Jenkinson* of real meaning, in

practice resurrecting the complete bar to a claim against equivalents for an amended patent that was rejected in those cases.

I. This Court Should Review The Federal Circuit's Much-Criticized View That It Owes No Deference To District Court Claim Constructions

The *de novo* standard of review, as applied indiscriminately to facts and technical mastery underlying claim construction, is a power grab by the Federal Circuit at the expense of the district courts and the judicial process. The standard, adhered to in three en banc decisions despite vociferous opposition from a substantial minority of the Federal Circuit[5] and criticism from the bench, bar, and beyond,[6] is overdue for further review.

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[5] In addition to the dissents from denial of rehearing in this case, see, *e.g.*, *Phillips* v. *AWH Corp.*, 415 F.3d 1303, 1330, 1334-35 (Fed. Cir. 2005) (en banc) (Mayer, J., dissenting) ("Now more than ever I am convinced of the futility, indeed the absurdity, of * * * adhering to the falsehood that claim construction is a matter of law devoid of any factual component."); *Cybor*, 138 F.3d at 1478 (Rader, J., dissenting) ("[T]his court misses the opportunity to improve certainty in patent practice by giving appropriate deference to trial court claim interpretations."); *Cybor*, 138 F.3d at 1480 (Newman, J., additional views) ("By continuing the fiction that there are no facts to be found in claim interpretation, we confound rather than ease the litigation process.").

[6] See, *e.g.*, Johnson, *The False Premise and Promises of* Markman *'s Decision To Task Judges with Claim Construction and the Judicial Scorecard*, Practising Law Institute (2005); Burgess, Comment, *Simplicity at the Cost of Clarity: Appellate Review of Claim Construction and the Failed Promise of* Cybor, 153 U. PA. L. REV. 763 (2004); Rooklidge & Weil, *Judicial Hyperactivity: The Federal Circuit's Discomfort with Its Appellate Role*, 15 BERKELEY TECH. L.J. 725 (2000); Am. Bar Ass'n *Amicus* Br., *Phillips* v. *AWH Corp.*, No. 03-1269, at 17-21, 2004 U.S. Fed. Cir. Briefs LEXIS 32 (Fed. Cir. Sept. 20, 2004); Fed. Cir. Bar Ass'n *Amicus* Br., *Phillips*, at 7-9; *Lucas Aerospace, Ltd.* v. *Unison Indus., L.P.*, 890 F. Supp. 329, 333 n.7 (D. Del. 1995) ("[W]hen the Federal Circuit * * * states that the trial court does not do something that the trial court does and must do to perform the judicial function, that court knowingly enters a land of sophistry and fiction.").

A. Claim Construction Entails Factual Inquiry, And This Case Is No Exception

1. The Federal Circuit held in *Markman* v. *Westview Instruments, Inc.*, 52 F.3d 967, 970-971, 981 (Fed. Cir. 1995) (en banc) ("*Markman I*"), aff'd on other grounds, 517 U.S. 370 (1996) ("*Markman II*"), that "the interpretation and construction of patent claims * * * is a matter of law exclusively for the Court." The Federal Circuit also asserted that claim construction entails no factfinding even though it depends on evidence (52 F.3d at 981): "By * * * using certain extrinsic evidence that the court finds helpful and resolving disputes en route to pronouncing the meaning of claim language * * * based on the patent documents themselves, the court is *not* crediting certain evidence over other evidence or making factual * * * findings."

Markman II agreed that claim construction is for the court, but pointedly did not agree that it is a purely legal endeavor. On the contrary, this Court characterized "construing a term of art following receipt of evidence" as a "mongrel practice" and recognized that "credibility judgments have to be made about the experts who testify in patent cases," but held that *trial* judges are "better suited" than juries to this activity because judges are trained "to evaluate the *testimony* in relation to the overall structure of the patent." 517 U.S. at 378, 389-390 (emphasis added). Accordingly, "there is sufficient reason to treat construction of terms of art like many other responsibilities that we cede to a judge in the normal course of trial, notwithstanding its *evidentiary underpinnings*." *Id.* at 390 (emphasis added). This Court, moreover, said nothing about the standard of appellate review of a judge's claim construction.

But the en banc Federal Circuit saw in *Markman II* what it wanted to see, and announced that the decision authorized it to "review claim construction *de novo* on appeal including any *allegedly fact-based questions*." *Cybor*, 138 F.3d at 1456 (emphasis added). That ruling is here to stay. Three years ago, the Federal Circuit invited briefing on whether "consistent with" *Markman II* and *Cybor* – in other words, *without*

reconsidering *Cybor* – the court of appeals owed "any deference to any aspect of trial court claim construction rulings." Even that question the court simply "decided not to address." *Phillips* v. *AWH Corp.*, 415 F.3d 1303, 1328 (Fed. Cir. 2005) (en banc), cert. denied, 126 S. Ct. 1332 (2006). And, again in this case, the en banc court showed no interest in reconsidering *Cybor*'s core holding.

2. Patents are written for those skilled in the art to which they pertain, *e.g.*, *W.L. Gore & Assocs., Inc.* v. *Garlock, Inc.*, 721 F.2d 1540, 1556 (Fed. Cir. 1983); 35 U.S.C. § 112, and so claim language must be interpreted "as one of skill in the art at the time of invention would understand" it. *Eastman Kodak Co.* v. *Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1555 (Fed. Cir. 1997). The trial court thus must determine: the state of the art as of the date of the invention; what the claim, in light of the specification, would mean to one of skill in the art; and what one of skill would understand from the statements the applicant made to the PTO to distinguish his invention from the prior art.

These are fundamentally assessments of fact, not law; they depend – as this Court acknowledged in *Markman II* – on *evidence*. See, *e.g.*, *Bayer AG* v. *Biovail Corp.*, 279 F.3d 1340, 1349 (Fed. Cir. 2002) ("[I]t would be premature for this court to engage in its own claim construction without * * * *evidence of the meaning of the terms* to one of skill in the art at the time of invention.") (emphasis added); see also *Markman I*, 52 F.3d at 999 (Newman, J., dissenting) ("[T]he meaning and scope of disputed technologic and other terms of art * * * are classic[] questions of fact.").[7] This Court also said as much in the

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[7] Judge Mayer's description of a *Markman* hearing is particularly revealing (*Phillips*, 415 F.3d at 1332 (dissenting opinion)):

> [P]arties battle over experts offering conflicting evidence regarding who qualifies as one of ordinary skill in the art; the meaning of patent terms to that person; the state of the art at the time of the invention; contradictory dictionary definitions and which would be consulted by the skilled artisan; the scope of specialized terms; the problem a patent was solving; what is related or pertinent art; * * *

context of obviousness under 35 U.S.C. § 103, when it labeled the following inquiries – which are similar to those necessary for claim construction – as factual: "the scope and content of the prior art," "differences between the prior art and the claims at issue," and "the level of ordinary skill in the pertinent art." *Graham* v. *John Deere Co.*, 383 U.S. 1, 17 (1966).

3. The Federal Circuit's mischaracterization of claim construction is responsible for what Judge Young called a "conundrum." App. 77a n.23. The Federal Circuit recognizes that expert testimony, dictionaries, and treatises "may be helpful to explain scientific principles, the meaning of technical terms, and terms of art that appear in the patent and prosecution history," and the state of the art at the time of the invention. *Markman I*, 52 F.3d at 980. But at the same time the court discourages district courts from relying on this extrinsic evidence. See, *e.g.*, *Phillips*, 415 F.3d at 1319; *Vitronics Corp.* v. *Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996). As Judge Young wondered: "How does a Court decipher the plain and customary meaning of a term as understood by one skilled in the art without resorting to extrinsic evidence about how one skilled in the art would construe the term?" App. 77a n.23. That paradox, acknowledged by Judges Rader and Moore in dissent below,[8] see pages 12-13, *supra*, is only enhanced when the Fed-

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> how one of skill in the art would understand statements during prosecution; and on and on. * * * [T]he district court is required to sift through and weigh volumes of evidence.

[8] Judge Rader also commented on this difficulty in *Cybor*, 138 F.3d at 1474-1475 (dissenting opinion) (citation omitted):

> [T]his court instructs experienced trial judges that they may use experts to understand, but not to interpret, the claim terms. As a matter of logic, this instruction is difficult to grasp. * * * [A] trial court must often resort to experts to learn complex new technologies. What happens when that learning influences a trial judge's interpretation of the claim terms? Are trial judges supposed to disguise the real reasons for their interpretation? How will this perverse incentive to "hide the ball" improve appellate review?

eral Circuit applies *de novo* review to constructions crucially informed by the very extrinsic sources to which the district court has superior access. The Federal Circuit tends, just as it did here, to ignore the extrinsic sources, see Dobrusin, *Post-Cybor: Can Past Performance Dictate Future Practice?*, IP LITIGATOR, Sept.-Oct. 1998, at 9-10 (Aspen Law & Business), and so its constructions are inevitably less accurate than those of the district court.

This is one of several reasons why Judge Gajarsa's concurrence in denial of rehearing is wide of the mark.[9] Judge Gajarsa took issue only with the periphery of *Cybor*, not its core, saying he would reconsider *Cybor* only to the extent that a district court has had to resolve *conflicting expert testimony*. But *Cybor*'s core is rotten, too: *all* claim constructions deserve at least some deference. Patents can be understood only with reference to technology, and the district judge who has immersed himself in that technology and its terminology – including by listening (as Judge Young did) to *non-conflicting* experts[10] – is in the best position to construe the patent.

Indeed, this case is an object lesson on the importance of deference. By the time he construed "therapeutically effective," Judge Young had received tutorials from an M.I.T. scientist, listened to 32 days of testimony from 35 scientists, and read countless pages of written submissions. His claim construction opinion repeatedly emphasized that his analysis was supported by his familiarity with the technology and the testimony of the parties' concurring scientific experts, which gave him key insights into – among many other things – the clinical significance of different signs of red blood cell generation.

For instance, after using dictionaries to establish a working assumption about the meaning of "therapeutically effective amount," Judge Young turned – as Federal Circuit precedent demands – to the language of the claims, his analysis of which

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[9] Another is discussed at page 22, *infra*.

[10] See page 8, *supra*.

was based on "a careful review of the technology and its history" that "relied on extrinsic evidence." Judge Young observed that, "[w]hile the Court cannot rely on expert testimony to help construe the term * * * unless absolutely necessary, it may look to the expert testimony to better understand the technology." He emphasized that his conclusions were informed by his "understanding of the technology," namely, his knowledge of the state of the art before Amgen's invention and the nature of Amgen's contribution. App. 84a-86a & n.28.

The same was true of Judge Young's reading of the specification. His task, as a matter of Federal Circuit precedent and especially in light of the first panel opinion, was to determine whether the specification, *read from the standpoint of one skilled in the art*, redefined "therapeutically effective" to require only certain biological effects besides an increase in hematocrit. In answering in the negative, he specifically noted that his reading "comports with the Court's understanding – developed over the course of two intensive trials – of what hematocrit actually measures. * * * [I]n *most* cases, an increase in hematocrit is accompanied, if not preceded, by 'any or all' of the biological effects listed in the specification." App. 91a.

Finally, Judge Young's analysis of the prosecution history for purposes of claim construction also drew on his intimate familiarity with this case. He explained that Amgen, to overcome rejections in the PTO, "differentiated its product from natural EPO * * * by asserting that natural EPO – which elicits the biological effects – was not therapeutically viable, whereas its product was clinically effective." App. 101a. Judge Young pointed out as well that the patent examiner must be presumed to have done his job, and that, "'if he truly thought that' Amgen's EPO" merely elicited the same effects as natural EPO, he would not have allowed the patent. App. 109a.

Judge Young thus understood, and the panel majority clearly did not, that *to skilled practitioners* numerous biological effects (an increase in the number of immature red blood cells,

for example) signal an increase in red blood cell production without *on their own* amounting to an increase in the total level of mature red blood cells. These effects, rather, are necessary precursors of the clinically useful result – the increase in hematocrit – which may or may not follow. In other words, the early indicators of red blood cell generation are necessary, but not sufficient, to treat anemia. Judge Young further understood that earlier EPO compositions, despite having reportedly induced some biological changes, were too impotent to increase hematocrit, which is how Amgen distinguished its product from the prior art in the first place. Armed with that knowledge, Judge Young concluded that, even though the specification associated certain biological changes with "therapy procedures," it would never occur to *a skilled practitioner reading the specification* that (as the panel majority thought) an amount *merely* eliciting one of these changes would be a "therapeutically effective amount." This was a factual determination, and it deserved deference.

4. Claim constructions should be reviewed in the same way as other conclusions entrusted to a judge but based on factual determinations. For example, validity under the nonobviousness standard of 35 U.S.C. § 103, though ultimately a question of law, rests on "several basic factual inquiries" akin to the inquiries underlying claim construction. See *Graham*, 383 U.S. at 17; pages 17-18, *supra*. Those inquires, under Rule 52(a), are reviewed only for clear error. *Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. 809 (1986). Similarly, under the Uniform Commercial Code, when a contract contains "usage of trade" terminology, "the existence and scope of such a usage are to be proved as facts," U.C.C. § 1-205, which are then reviewed for clear error. *E.g.*, *Voest-Alpine Trading USA Corp.* v. *Bank of China*, 288 F.3d 262, 265 (5th Cir. 2002). The law abounds with other examples of deferential appellate review of the facts undergirding a legal conclusion. See, *e.g.*, *Ornelas* v. *United States*, 517 U.S. 690, 699 (1996) (facts underlying judge's determination of probable cause are reviewed for clear error); *United States* v. *Bajakajian*, 524 U.S. 321, 337 n.10 (1998)

(same for factual findings made in inquiring into excessiveness of a fine). Claim constructions should be treated the same way.

Nor should the standard of review depend, as Judge Gajarsa's concurrence suggested, on whether the district court's claim construction makes use of live testimony. There is no reason to believe that when this Court acknowledged the "evidentiary underpinnings" of claim construction, *Markman II*, 517 U.S. at 390, it had only extrinsic evidence in mind. The patent and, especially, its prosecution history – though documentary in nature – are still *evidence* from which a tribunal must make case-specific findings, not just announce principles of law. And it is settled that federal judges' factual findings are reviewed for clear error even when based only on documentary evidence. FED. R. CIV. P. 52(a); *Anderson* v. *Bessemer City*, 470 U.S. 564, 574 (1985).

B. District Courts Are Institutionally "Better Positioned" Than Appellate Courts To Construe Patent Claims

Markman II was based on "'a determination that, as a matter of the sound administration of justice,'" a judge is "'better positioned'" than a jury to construe patent claims, 517 U.S. at 388. Similarly, the standard of appellate review "should depend upon 'the respective institutional advantages of trial and appellate courts.'" *First Options of Chicago, Inc.* v. *Kaplan*, 514 U.S. 938, 948 (1995); see also *Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 402-404 (1990); *Pierce* v. *Underwood*, 487 U.S. 552, 559-560 (1988). In claim construction, there can be no question where the advantage lies, for district judges have superior tools for educating themselves on technology. They can question the parties' experts, appoint their own experts, receive tutorials from scientists, call for whatever submissions are necessary, and even conduct on-site visits (see *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 339 U.S. 605, 611 (1950)).

This Court has expressed firm confidence in district judges' ability to handle complex technical issues. *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), instructs district judges to ascertain the reliability of expert

testimony, even though that sometimes requires them "to make subtle and sophisticated determinations about scientific methodology," *General Electric Co.* v. *Joiner*, 522 U.S. 136, 147 (1997) (Breyer, J., concurring).[11] This Court nevertheless said it was "confident that federal [district] judges possess the capacity to undertake this review." 509 U.S. at 593. The *Markman* procedure in many ways is analogous to the *Daubert* procedure – both require a judge to assimilate and evaluate technical information. But, whereas *Daubert*'s vote of confidence culminated in *Joiner* – which held that a *Daubert* decision is reviewed only for abuse of discretion, 522 U.S. at 146 – the Federal Circuit substitutes its judgment for that of the district court in every case in which *de novo* review prompts two appellate judges to reach a different conclusion.

In *Markman I*, the Federal Circuit analogized claim construction to statutory construction, 52 F.3d at 987, apparently believing, as Judge Gajarsa's concurrence asserts, that trial and appellate courts are "equally competent" to interpret patent documents. App. 607a. That analogy is not only questionable under Rule 52(a) and *Anderson* v. *Bessemer City*, *supra* – which require appellate deference to factual findings based purely on documentary evidence – but flawed on its own terms. As Chief Judge Michel's dissent from denial of rehearing explains, appellate judges, as "artisans in the law," may indeed be equally competent to construe a statute but are at a distinct disadvantage when it comes to putting themselves in the position of one of ordinary skill in a scientific or technical discipline. App. 596a.

A compelling illustration of this point is the panel majority's performance in this very case. The majority failed to grasp

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[11] Justice Breyer commented approvingly in *Joiner* on the use of technical advisors and special masters to help make determinations about "complicated scientific, or otherwise technical, evidence." 522 U.S. at 149. Judge Young – unlike the panel – benefited from both a technical advisor and a special master. See pages 5 and 7, *supra*.

basic concepts like what hematocrit measures,[12] radically misread the specification, and then gave the claims a naïvely broad meaning that ignored the precise features that distinguished the invention from what was already known. The majority did not appreciate that, *from the standpoint of a skilled practitioner*, Dr. Lin's discussion of biological effects in connection with "therapy procedures" would not convert each of those effects into a "therapeutically effective" result. Saying that something is "suitable for use in erythropoietin therapy procedures * * * to develop * * * effects here[to]fore attributed to" EPO is not at all the same thing as saying that merely producing one of those effects is equivalent to therapeutic effectiveness. It is to avoid just this sort of mistake, made by appellate judges who cannot possibly learn the technology as deeply as an able trial judge, that deference is "particularly" called for when "so much depends upon familiarity with specific scientific problems and principles." *Graver Tank*, 339 U.S. at 610.

The panel was even more confused about the passage it raised *sua sponte*, which said that various EPO fragments or relatives that are *not* the subject of the claim at issue can have "therapeutic utility" even if they produce no in vivo effects on their own. The majority, apparently without consulting the citation in the passage, see note 4, *supra*, and overlooking the fact that "therapeutic utility" and "therapeutically effective" are different terms, believed this was evidence that the patentee "did not use the word 'therapy' in order to limit the scope of the '422 patent to only EPO that cured disease," App. 15a – even though that is a total non sequitur and ignores the *majority*'s notion that "therapeutic effectiveness" is equivalent to the in vivo effects. Errors like this are inevitable when appellate courts, which do not have the benefit of all the submissions and testimony available to the district court, embark on their own factfinding.

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[12] The majority thought hematocrit is the "ratio of red blood cells to total blood cells." App. 5a. Hematocrit is rather the ratio of red blood cell *volume* to total blood *volume* – not at all the same thing.

C. This Issue Has Paramount Importance For Patent Litigation And Is Ripe For Review By This Court

This case readily qualifies for further review. Not only is the Federal Circuit profoundly and irreconcilably divided, a circumstance that in the past has prompted review in this Court,[13] but the question presented is surpassingly important. *De novo* review misallocates judicial resources, spawns needless disputes, prolongs litigation, and destroys certainty.

De novo review misallocates judicial resources because appellate courts usually cannot replicate the factual understanding of the district courts, see *Pierce*, 487 U.S. at 560, which may be why more than one-third of claim constructions are being reversed on appeal.[14] This enormous reversal rate confounds and demoralizes district judges.[15] Moreover, as this case highlights, an appellate do-over wastes the often-large investment in the trial judge's education. See, *e.g.*, Lueders et al., *Refining* Cybor, INTELL. PROP. TODAY, Nov. 2006, at 17, 18. It is precisely to avoid problems like this that Rule 52(a) mandates deference even to documentary-based findings. See Rule 52 Adv. Comm. notes ("To permit courts of appeals to share more actively in the fact-finding function would tend to undermine the legitimacy of the district courts in the eyes of litigants, multiply appeals by encouraging appellate retrial of

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[13] See *Warner-Jenkinson*, 520 U.S. at 21 (review warranted given "[t]he significant disagreement within the * * * Federal Circuit"); see also *Festo*, 535 U.S. at 730 (four judges in four opinions dissented from en banc decision); *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 88 (1993) (three dissents from denial of rehearing en banc).

[14] Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 233 (2005).

[15] See *A Panel Discussion: Claim Construction from the Perspective of the District Judge*, 54 CASE W. RES. L. REV. 671, 672 (2004) ("[S]ometimes we think that the only thing that really is predictable in this area of the law is that we district judges will likely get it wrong, or at least that the Federal Circuit will say that we got it wrong.").

some factual issues, and needlessly reallocate judicial authority.").

De novo review also makes litigation exceptionally costly for the parties. Definitive claim constructions tend to promote settlement: "Once the parties know the meaning of the claims, they can predict with some reliability the likelihood of a favorable judgment, factor in the economics of the infringement, and arrive at a settlement to save the costs of litigation." *Cybor*, 138 F.3d at 1475 (Rader, J., dissenting). But when every claim construction is revisited *de novo* in the Federal Circuit – where the odds of reversal are huge and a "sporting element" is created by "unexpectedly creative de novo claim interpretations," *Cybor*, 138 F.3d at 1479 (Newman, J., additional views) – prediction becomes impossible until after the appeal is decided. What is more, at that point a whole new trial under a new claim construction may be necessary, just as it is in this case. Finally, the current regime creates an incentive to contest every possible claim term, hoping that at least one argument might succeed on appeal. See *Cybor*, 138 F.3d 1476 (Rader, J., dissenting) ("As the focus shifts * * * to preserving ways to compel reversal on appeal, the uncertainty, cost, and duration of patent litigation only increase."). Here, for example, "therapeutically effective," though not even on the list of the top ten disputed terms for the first *Markman* hearing, see App. 430a, remains in dispute a decade after this litigation began.

II. This Court Should Review The Federal Circuit's Near Abolition Of The Doctrine Of Equivalents In Any Case In Which A Patent Has Been Amended

This Court has long recognized that patent protection would be meaningless if an imitator could circumvent a patent by making "unimportant and insubstantial changes and substitutions" to the invention. *Graver Tank*, 339 U.S. at 607 (citing *Winans* v. *Denmead*, 56 U.S. (15 How.) 330 (1854)). Just as Judge Young found with respect to the single amino acid discrepancy at issue here, "[t]he language in the patent claims may not capture every nuance of the invention or describe with

complete precision the range of its novelty." *Festo*, 535 U.S. at 731. Accordingly, "[t]he scope of a patent is not limited to its literal terms but instead embraces all equivalents to the claims." *Id.* at 732. At the same time, this Court has recognized that the doctrine of equivalents is in tension with the public notice function of patents. *Ibid.* However, rather than accept repeated invitations to "speak the death" of the doctrine, *Warner-Jenkinson*, 520 U.S. at 21, the Court has endeavored to reconcile the competing interests. Thus *Festo* clarified that a narrowing amendment to a patent claim during prosecution presumptively surrenders equivalents to the amended claim that would have been literally covered by the unamended version.

The rebuttability of this presumption is essential. *Warner-Jenkinson* rejected a "rigid rule invoking an estoppel regardless of the reasons for" amendment. 520 U.S. at 32. And *Festo* reversed a highly formalistic Federal Circuit decision holding that prosecution history estoppel is a complete bar to a claim of infringement by equivalents. *Festo* explained that the bar should not apply when "the amendment cannot reasonably be viewed as surrendering a particular equivalent," as when (1) the equivalent was "unforeseeable at the time of the application"; (2) "the rationale underlying the amendment * * * bear[s] no more than a tangential relation to the equivalent in question"; or (3) "some other reason suggest[s] that the patentee could not reasonably be expected to have described the insubstantial substitute in question." 535 U.S. at 740-741. Yet the Federal Circuit has been virtually heedless of these pronouncements.

A. The most significant of the three *Festo* criteria is the second, which deals with the relationship between the rationale for amendment and the equivalent at issue. The court of appeals' entire reasoning under this criterion is contained in this non sequitur: "[T]he [reference to the Figure 6 sequence] added in the * * * amendment may have been central to overcoming a double patenting rejection in light of claim 1 of the '933 patent. Under these circumstances we cannot say that the reason for the [amendment] was merely tangential to the alleged 165-amino acid equivalent." App. 37a-38a. But it was already

established that the amendment was designed to avoid a double-patenting rejection. The question under *Festo* is rather whether that *reason* – the need to avoid duplication – has any significant relationship to the distinction between 165 and 166 amino acids. As Judge Young determined – after careful examination of the prosecution history informed by technical conversance that the court of appeals lacked – it does not. App. 318a-323a. The amendment simply was not made to distinguish a polypeptide having 165 amino acids from one having 166.

In focusing on the *result* of the amendment rather than its purpose, the court of appeals erected a roadblock across the most important avenue for avoiding estoppel. As Judge Young explained when TKT committed the same fallacy in the district court, this mode of analysis conflates two things: (1) the relationship between the reason for the amendment and issues of patentability, and (2) the relationship between the reason for amendment and the equivalent in question. The rationale for amendment "cannot be more than tangentially related to" the equivalent in question, "but it *can* be more than tangentially related to patentability issues" – after all, it is because of the relationship to patentability that the presumption of estoppel arises in the first place. In ruling to the contrary, the court of appeals made this crucial standard "circular and insurmountable." App. 323a. More recently, the Federal Circuit has held "that the tangential relation criterion for overcoming the *Festo* presumption is very narrow" and vacated yet another district court decision accepting a rebuttal case under that criterion. *Cross Med. Prods., Inc.* v. *Medtronic Sofamor Danek, Inc.*, No. 05-1415, 2007 WL 817660, at *5 (Fed. Cir. Mar. 20, 2007).

The Federal Circuit also destroyed the residual *Festo* criterion dealing with whether the patentee could "reasonably be expected to have described" the equivalent. Judge Young found that the patentee, the examiner, and a hypothetical person of skill in the art all understood the amended claim to encompass a 165-amino-acid polypeptide. "It is not reasonable to expect * * * different claim language when the language that was used was interpreted by those skilled in the art to be sufficiently de-

scriptive." App. 333a. And yet the panel reversed because there was no "linguistic barrier" to claiming the equivalent.

But that is not the issue. As Judge Young explained: "If the question was merely whether the patentee *could* have drafted a claim to encompass the equivalent then the test would simply be a foreseeability test," and there would have been no need for other *Festo* criteria. App. 295 n.13. The whole point of the residual criterion is to "soften[] the harsh standard that may be inherent in the foreseeability test. After all, it may be *unreasonable* to require the patentee to exhaust every arguably foreseeable equivalent in the world." Fu, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 18 BERKELEY TECH. L.J. 117, 137 (2003) (emphasis added). Indeed, the foreseeability standard has not succeeded in one appellate decision since *Festo*. Thus the court of appeals has collapsed the *Festo* criteria into ones with no practical application, effectively reviving the complete-bar rule this Court rejected in *Festo*.

B. Moreover, the court of appeals' aggressive disregard for Judge Young's prosecution history estoppel rulings is of a piece with its disdain for trial court claim constructions. As Judge Young pointed out (App. 292a n.11), treating a finding on prosecution history estoppel as a pure question of law reviewable *de novo* on appeal has deleterious consequences comparable to those in the claim construction context.

Festo contemplated that a patentee could "show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." 535 U.S. at 741. Because the prosecution history and specification alone cannot possibly permit such a demonstration, this Court clearly was calling for an inquiry into factual and technological circumstances. The en banc Federal Circuit even acknowledged on remand from *Festo* that "rebuttal of the presumption may be subject to underlying facts." *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1368 n.3 (Fed. Cir. 2003). Sure enough, Judge Young's decision was informed by

his technical familiarity and evidence of the understanding of skilled artisans. And even though TKT – which *lost* in the district court – conceded during argument that the factual components of a *Festo* determination deserve deference, the Federal Circuit insists on subjecting *Festo* rulings, including Judge Young's, App. 33a, to indiscriminate *de novo* review.[16] This practice violates bedrock principles of appellate review.[17]

The doctrine of equivalents and prosecution history estoppel have vast importance for patent litigation and prosecution. "Outright and forthright duplication is a * * * very rare type of infringement," *Graver Tank*, 339 U.S. at 607, and so a great deal of patent litigation concerns the doctrine of equivalents. *E.g.*, Teague, *Festo and the Future of the Doctrine of Equivalents*, 3 CHI.-KENT J. INTELL. PROP. 1, 16 (2003). Similarly, the vast majority of patents are amended during prosecution.[18] Indeed, this Court chose to hear *Festo* and *Warner-Jenkinson* in part because these two doctrines define so much of the scope of patent protection and influence so heavily applicants' behavior during the application process. This petition, therefore, raising as it does the question whether the Federal Circuit has adopted through the back door the same rule this Court rejected in *Festo*, presents a question no less important than *Festo* did.

CONCLUSION

The petition for a writ of certiorari should be granted.

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[16] *E.g.*, *Conoco, Inc.* v. *Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1357 (2006); *Rhodia Chimie* v. *PPG Indus. Inc.*, 402 F.3d 1371, 1376 (2005); *Ranbaxy Pharms., Inc.* v. *Apotex, Inc.*, 350 F.3d 1235, 1240 (2003).

[17] The practice also runs counter to the United States' position. On remand in *Festo*, the United States explained that the Federal Circuit "should accord considerable deference to the district court's resolution of" subsidiary questions of fact supporting a *Festo* determination because of the respective advantages of trial and appellate courts. U.S. *Amicus* Br. 6-7, No. 95-1066, 2002 WL 32144415 (Fed. Cir. Nov. 2002).

[18] See, *e.g.*, *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 638 n.3 (Fed. Cir. 2000) (en banc) (Newman, J., dissenting).

Respectfully submitted.

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